REMARKS

Claims 1-27 are pending in the application. Claims 1-13 and 25-27 are rejected. Claims 14-24 are withdrawn from consideration. No claims are allowed.

Claims 1, 10 and 25 have been amended to more clearly describe and distinctly claim the subject matter Applicants consider their invention. Specifically, claims 1 and 25 have been amended to delete reference to "the ratio of the inside diameter of said chamber to the diameter of said passageway."

Claim 1 has also been amended specify that the fluid solution in the chamber is in an amount less than 10 ml. Support for the amendment can be found in the specification as originally filed at, *e.g.*, page 8, paragraphs 0032, 0034; page 10, paragraphs 0040-0041.

Claim 25 has also been amended to delete an inadvertent duplication of "in the range of."

Claim 10 has been amended to replace "14.43 mm (0.568 inch)" with "approximately 14.5 mm (0.57 inch)." Support for the amendment can be found in the specification as originally filed at, *e.g.*, page 2, paragraph 0004.

No new material has been added by this amendment.

Claims 1-13 and 25-27 are presented for further proceedings. Reconsideration of the claim rejections and allowance of the pending claims in view of the amendments above and following remarks are respectfully requested.

Claim Rejections – 35 U.S.C. § 112

a. Claims 1-13 and 25-27 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement and written description requirements.

According to the Examiner, there is no description of selecting a ratio of the inside diameter of the chamber to the diameter of the passageway such that the fluid pressure in the flush solution injected through the passageway is less 40 psi when a ten pound force is applied to the plunger.

Claims 1 and 25 (the only remaining independent claims under examination) have been amended to delete reference to the ratio of the inside diameter of said chamber to the diameter of said passageway. Accordingly, Applicants respectfully request that the rejection be withdrawn.

b. Claim 10 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. According to the Examiner, there is no description of an inside diameter of 14.43 mm (0.568 inch).

Claim 10 has been amended to replace "14.43 mm (0.568 inch)" with "approximately 14.5 mm (0.57 inch)," for which there is support at page 2, paragraph 0004, of the specification as originally filed. Accordingly, Applicants respectfully request that the rejection be withdrawn.

c. Claims 1-13 and 25-27 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. According to the Examiner, the limitation "said chamber having an inside diameter of at least 13.5 mm (0.53 inch)" essentially claims that any chamber diameter above 13.5 mm will be suitable for making the syringe. The Examiner concludes that such an unrestricted range renders the claim indefinite.

Applicants respectfully traverse this basis for rejection.

The Examiner apparently believes that because there is no upper limit recited in the limitation at issue, inside diameters could be chosen which would make the resulting

syringe unsuitable for use, thereby rendering the claim indefinite. However, the fact that a claim recites an open-ended range which reads on a large number of values does not in itself render a claim indefinite. *See In re Miller*, 441 F.2d 689, 693 (CCPA 1971) ("[B]readth is not to be equated with indefiniteness"). Applicants submit that there is nothing indefinite about "said chamber having an inside diameter of at least 13.5 mm (0.53 inch)," regardless of its breadth. Each of the claim terms are unambiguous and clearly understood by those skilled in the art, and the Examiner has provided no evidence to the contrary. *See In re Fisher*, 427 F.2d 833, 838 (CCPA 1970) ("Here the examiner and the board have viewed the absence of a limitation as to amino acids beyond the 24th position as rendering the claim indefinite. While the absence of such a limitation obviously broadens the claim . . ., it does not render the claim indefinite. The absence of the limitation has a precise meaning."); *In re Wakefield*, 422 F.2d 897, 904 (CCPA 1970) ("The complaint [of the Board] seems to be that a very large number of substances are encompassed by the claims, through the possible addition of unrecited impurities. The scope of the claim is still definite, however, because each recited limitation is definite.").

Furthermore, reading the limitation at issue to include values which would render the claimed syringe assembly inoperative, as the Examiner has done, distorts the plain meaning of the claims, particularly given that they also require that the length of the barrel chamber be no more than 57 mm (2.25 inches). This combination of values, along with the other limitations in the claims, clearly allows one of skill in the art to make and use a functional syringe having the required fluid pressure in the flush solution. *See Cedarapids, Inc. ex rel. El-Jay Div. v. Nordberg, Inc.*, Appeal No. 95-1529, 1997 U.S. App. LEXIS 21157, at *11 (Fed. Cir. Aug. 11, 1997) ("Claim 1 covers a method of

increasing crusher performance by simultaneously increasing the speed and throw. The language itself requiring "simultaneously increasing" is not ambiguous except as to the amounts of the required increases. Those, of course, will vary with the size of the crusher involved and with the point of optimum performance. In the specification, the amount of increase for a seven foot crusher is shown, and, with some experimentation, the amounts for other size crushers are determinable by those skilled in the art."); *In re Kirsh*, 498 F.2d 1389, 1394-95 (CCPA 1974) ("The rejection is based on the view that the language of the recitation sets only a maximum amount of olefin and hence "is inclusive of substantially no olefin, resulting in the termination of any reaction." We see no merit in this rejection. The claim requires a process for the preparation of olefin-paraffin alkylate by contacting the two reactants under defined conditions. The imposition of a maximum limit on the quantity of one of the reactants without specifying a minimum does not warrant distorting the overall meaning of the claim, to preclude performing the claimed process.").

Accordingly, because each of the claim terms in the limitation at issue is unambiguous and has a clear meaning in the art, Applicants submit that claims 1-13 and 25-27 are not indefinite, and reconsideration of this basis for rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 1-13 and 25-27 are rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Howe (US 5,242,405). According to the Examiner, Howe discloses a syringe (20) comprising a syringe barrel (21) having an elongated body and chamber, an open proximal end, a distal end (33) and a frusto-conically shaped tip (34) extending

from the distal end having a tip passageway therethrough in fluid communication with the chamber, a rubber stopper (39) in fluid- tight engagement inside the barrel, an elongated plunger rod (40) defining a longitudinal axis and extending proximally from the stopper through the open end, and a flange (not numbered) at the proximal end, a tip cap (44) for sealing the passageway, and a flush solution (43) in the chamber, and the barrel includes measuring indicia (35a).

The Examiner acknowledges that Howe does not specifically disclose the recited diameter or length of the chamber, or the limitation "the ratio of the inside diameter of said chamber to the diameter of said passageway being selected such that the fluid pressure in the flush solution injected through the passageway is less than 40 psi when a ten pound force is applied to the plunger rod." However, according to the Examiner, these limitations are not being given patentable weight because the standard size of a syringe is larger than 13.5 mm and therefore if the syringe barrel of Howe is not inherently greater than 13.5 mm, it would certainly be obvious to modify the barrel to this size. In regard to the recited length, the Examiner is interpreting this limitation to be an obvious modification as a mere change in the size and/or shape of the prior art device. According to the Examiner, the length of the syringe barrel does not appear to be involved in the reduced pressure of the flush solution, as Applicants claim that it is the ratio between the chamber diameter and passageway diameter that results in a reduced pressure. The Examiner concludes that one of ordinary skill in the art would find it obvious to modify the dimensions of the syringe barrel to adjust the pressure of the output fluid.

Applicants respectfully traverse this basis for rejection.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), *viz.*, (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 985 (CCPA 1974). Furthermore, although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

Claim 1

Claim 1 is directed to an I.V. flush syringe assembly comprising, *inter alia*, a) a syringe barrel having an elongated body defining a chamber having flush solution in an amount less than 10 ml therein and a frusto-conical tip having passageway therethrough in fluid communication with the chamber, the chamber having an inside diameter of at

least 13.5 mm (0.53 inch), the length of said chamber being no more than 57 mm (2.25 inches); b) a stopper; c) a plunger rod; and d) a tip cap, wherein the pressure of the flush solution injected through the passageway is less than 40 psi when 10 pounds of force is applied to the plunger rod. By providing an inside diameter of at least 13.5 mm, which is on the order of a traditional 10 mL flush syringe, fluid pressures produced by traditional 1, 3 and 5 mL flush syringes are maintained at or below those produced by a traditional 10 mL flush syringe assembly. *See* page 2, paragraph 0004. A major advantage of such a flush syringe assembly is that the fluid pressure will be only about one-third of the fluid pressure if, e.g., a prior art 3 ml syringe were being used with the same force being applied to the plunger rod. The reduced pressure makes it easier for the user to determine if the catheter is open and reduces the possibility of dislodging a clot or rupturing the catheter. In addition, if larger volume syringes having the same diameter are used, the general feel of the syringe and the technique will remain consistent from syringe to syringe so that the feel and the touch and the forces applied in flushing the catheter with a 3 ml syringe of the present invention are the same as a 10 ml syringe having the same diameter. *See* page 8, paragraph 0034. In this way, a family of flush syringes can be provided, each with diameters on the order of a traditional 10 mL flush syringe but containing different amounts of flush solution, thus allowing optimal pressure distribution to be achieved with all volumes. *See* page 10, paragraph 0041.

In contrast to the flush syringe assembly of claim 1, and as acknowledged by the Examiner, Howe merely discloses what appears to be a standard syringe. Howe does not disclose the inside diameter of the barrel (let alone that it is least 13.5 mm (0.53 inch)) or the length of the barrel chamber (let alone that it is no more than 57 mm (2.25 inches)).

However, the Examiner has refused to give these limitations any patentable weight. With regard to diameter, the Examiner states the standard inside diameter of a syringe is larger than 13.5 mm and therefore if the syringe barrel of Howe is not inherently greater than 13.5 mm, it would certainly be obvious to modify the barrel to this size. Applicants acknowledge that the inside diameter of a standard ***10 mL*** flush syringe is larger than 13.5 mm. However, the claim now recites that the flush syringe contains ***less than*** 10 mL flush solution, an amount which traditionally was contained in syringes having an inside diameter less than 13.5 mm. *See* page 2, paragraph 0004.

With regard to length, the Examiner states that the length of the barrel is being interpreted to be an obvious modification as a mere change in the size and/or shape of the prior art device. According to the Examiner, the length of the syringe barrel does not appear to be involved in the reduced pressure of the flush solution, as Applicants claim that it is the ratio between the chamber diameter and passageway diameter that results in a reduced pressure. Claim 1 has been amended to delete reference to the ratio between the chamber diameter and passageway diameter. As now claimed, the length of the barrel chamber is related to fluid pressure in the sense that the increased inside diameter of the claimed flush syringe (in relation to a traditional 10 mL syringe) allows the length of the barrel to be reduced to no more than 57 mm (2.25 inches) and still deliver the same volume of fluid as traditional syringes but with reduced fluid pressures. In this way, the benefits of a traditional 10 mL syringe are obtained but with reduced disposal costs, since shorter syringes take up less disposal container space.

As such, Applicants submit that the claimed dimensions are deserving of patentable weight, and their combination is neither taught nor suggested by the standard

syringe disclosed in Howe. *See In re Pelosi, Jr.*, Appeal No. 1999-1813, for U.S. Pat. Appl. No. 08/801,010, at 5-6 (BPAI 2001) ("[T]he specific limitation regarding the taper of the appellant's device [with the claimed dimensions] is not merely a matter of design choice, as the examiner has stated, but constitutes a solution to a problem existing in the art."). Accordingly, Applicants submit that claim 1 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 2

Claim 2 is directed to the flush syringe assembly of claim 1, wherein the length of the syringe barrel is in the range of 38.1 mm (1.5 inches) and 44.5 mm (1.75 inches). Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987). Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested a flush syringe having the narrower dimensions recited in claim 2.

Accordingly, Applicants submit that claim 2 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 3

Claim 3 is ultimately directed to the flush syringe assembly of claim 1, wherein the chamber contains no more than 3.5 ml of flush solution. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows

Howe would also have not have suggested such a flush syringe containing no more than 3.5 ml of flush solution.

Accordingly, Applicants submit that claim 3 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 4

Claim 4 is directed is directed to the flush syringe assembly of claim 1, wherein the flush solution is selected from the group consisting of saline flush solution and heparin lock flush solution. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested such a flush syringe containing saline flush solution or heparin lock flush solution.

Accordingly, Applicants submit that claim 4 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 5

Claim 5 is directed to the flush syringe assembly of claim 1, wherein the syringe assembly is contained in a package which provides a tamper evident barrier surrounding the syringe assembly. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested such a flush syringe contained in a package which provides a tamper evident

barrier surrounding the syringe assembly. Furthermore, the Examiner has pointed to nothing in Howe or the art in general that teaches or suggests a package which provides a tamper evident barrier. *See Smiths Indus. Med. Sys. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356 (Fed. Cir. 1999) ("That knowledge *may* have been within the province of the ordinary artisan does not in and of itself make it so, absent clear and convincing evidence of such knowledge.") (emphasis in original).

Accordingly, Applicants submit that claim 5 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 6

Claim 6 is directed to the flush syringe assembly of claim 1, wherein the syringe assembly is contained in a package which provides a sterile barrier surrounding the syringe assembly. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested such a flush syringe contained in a package which provides a sterile barrier surrounding the syringe assembly. Furthermore, the Examiner has pointed to nothing in Howe or the art in general that teaches or suggests a package which provides a sterile barrier. *See Smiths*, 183 F.3d at 1356.

Accordingly, Applicants submit that claim 6 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 7

Claim 7 is directed to the flush syringe assembly of claim 1, further including volume measuring indicia on the barrel. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested such a flush syringe further including volume measuring indicia on the barrel.

Accordingly, Applicants submit that claim 7 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 8

Claim 8 is ultimately directed to the flush syringe assembly of claim 1, further including volume measuring indicia on the barrel which indicates the stopper position for a chamber volume of about 3 ml. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested such a flush syringe further including volume measuring indicia on the barrel which indicates the stopper position for a chamber volume of about 3 ml.

Accordingly, Applicants submit that claim 8 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 9

Claim 9 is directed to the flush syringe assembly of claim 1, wherein the stopper is made of material selected from the group of natural rubber, synthetic rubber, thermoplastic elastomers and combinations thereof. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested such a flush syringe wherein the stopper is made of material selected from the group of natural rubber, synthetic rubber, thermoplastic elastomers and combinations thereof.

Accordingly, Applicants submit that claim 9 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 10

Claim 10 is directed to the flush syringe assembly of claim 1, wherein the inside diameter of the chamber is approximately 14.5 mm (0.57 inch). Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested a flush syringe having the narrower dimensions recited in claim 10.

Accordingly, Applicants submit that claim 10 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 11

Claim 11 is directed to the flush syringe assembly of claim 1, wherein the plunger rod flange is smaller than the open proximal end of the barrel when measured in a direction perpendicular to the longitudinal axis so that the plunger rod flange does not extend radially beyond the barrel. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested such a flush syringe wherein the plunger rod flange is smaller than the open proximal end of the barrel when measured in a direction perpendicular to the longitudinal axis so that the plunger rod flange does not extend radially beyond the barrel.

Accordingly, Applicants submit that claim 11 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 12

Claim 12 is ultimately directed to the flush syringe assembly of claim 1, wherein the stopper and plunger rod are dimensioned so that when the plunger rod flange contacts the proximal end of the barrel there is a space between at least a portion of the distal end of the stopper and the distal wall of the barrel. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested such a flush syringe wherein the stopper and plunger rod are

dimensioned so that when the plunger rod flange contacts the proximal end of the barrel there is a space between at least a portion of the distal end of the stopper and the distal wall of the barrel.

Furthermore, the Examiner has pointed to nothing in Howe or the art in general that would have suggested to one of skill in the art a stopper and plunger rod dimensioned so that when the plunger rod flange contacts the proximal end of the barrel there is a space between at least a portion of the distal end of the stopper and the distal wall of the barrel. *See Smiths*, 183 F.3d at 1356. As explained in the instant application, this configuration prevents the stopper from being excessively compressed against the distal chamber wall, thereby preventing the stopper from expanding following fluid delivery and possibly pulling fluid back from the catheter and allowing blood to enter the catheter tip. *See* page 9, paragraph 0037. Applicants submit that such a configuration is unobvious over the art of record.

Accordingly, Applicants submit that claim 12 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 13

Claim 13 is directed to the flush syringe assembly of claim 1, wherein the plunger rod includes a threaded extension projecting from the distal end of the plunger rod and the stopper defines a threaded recess which engages with the threaded extension of the plunger rod. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested a flush syringe having the dimensions recited in claim 1, it necessarily follows Howe would also have not have suggested such a

flush syringe wherein the plunger rod includes a threaded extension projecting from the distal end of the plunger rod and the stopper defines a threaded recess which engages with the threaded extension of the plunger rod.

Accordingly, Applicants submit that claim 13 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claims 25

Claim 25 is directed to a catheter flush kit comprising, *inter alia*, a) a first syringe assembly having a chamber length in the range of 38.1 mm (1.5 inches) to 44.5 mm (1.75 inches) and an inside diameter of at least 13.5 mm (0.53 inch) and including no more than about 3.3 ml of a first flush solution in the chamber, wherein the fluid pressure in the flush solution injected through the passageway in the chamber is less than 40 psi when a ten pound force is applied to the plunger rod; and b) a second syringe assembly having a chamber with an inside diameter of at least 13.5 mm (0.53 inch) and having no more than about 10ml of a second flush solution in the chamber. Such a kit constitutes a family of flush syringes, each with diameters on the order of a traditional 10 mL flush syringe but containing different amounts of flush solution, thus allowing optimal pressure distribution to be achieved with all volumes. *See* page 10, paragraph 0041.

According to the Examiner, Howe discloses the claimed invention except for multiple syringe barrels, which would have been obvious as a mere design consideration. However, as discussed above with respect to claim 1, Howe would not have suggested a flush syringe having the recited dimensions of the first syringe assembly and including no more than 3.3 mL of flush solution. Fluid pressure for such a flush syringe will be only about 1/3 that of a traditional 3 mL flush syringe, thereby providing a general feel and

touch similar to that of a traditional 10 mL flush syringe and making it easier to determine if the catheter is open and reducing the possibility of clot dislodgment or catheter rupture. *See* page 8, paragraph 0034. It necessarily follows then that Howe also would not have suggested including a second syringe assembly having the recited dimensions of the first syringe assembly and including no more than about 10 ml of flush solution. Consequently, Howe would not have suggested providing a family of syringe assemblies, each containing different amounts of flush solution but each with diameters on the order of a traditional 10 mL flush syringe, thereby each producing a fluid pressure of less than 40 psi when a ten pound force is applied to the plunger rod.

Accordingly, Applicants submit that claim 25 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 26

Claim 26 is directed to the catheter flush kit of claim 25, wherein the syringe assemblies are contained in a package which provides a tamper evident barrier surrounding the syringe assemblies. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested the catheter flush kit recited in claim 25, it necessarily follows Howe would also have not have suggested such a flush kit contained in a package which provides a tamper evident barrier surrounding the syringe assemblies. Furthermore, the Examiner has pointed to nothing in Howe or the art in general that teaches or suggests a package which provides a tamper evident barrier. *See Smiths*, 183 F.3d at 1356.

Accordingly, Applicants submit that claim 26 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

Claim 27

Claim 27 is ultimately directed to the catheter flush kit of claim 25, wherein the plunger rod flange in at least one of the syringe assembles is shaped and positioned to limit the distal motion of the plunger rod in the barrel by contacting the proximal end of the barrel. Where an independent claim is valid over cited art, *a fortiori* any claim dependent therefrom must also be valid over the same art. *See Panduit*, 810 F.2d at 1576 n.36. Because Howe would not have suggested the catheter flush kit recited in claim 25, it necessarily follows Howe would also have not have suggested such a flush kit wherein the plunger rod flange in at least one of the syringe assembles is shaped and positioned to limit the distal motion of the plunger rod in the barrel by contacting the proximal end of the barrel.

Accordingly, Applicants submit that claim 27 is not unpatentable over Howe, and reconsideration of this basis for rejection is respectfully requested.

CONCLUSION

It is believed that claims 1-13 and 25-27 are now in condition for allowance, early notice of which would be appreciated. No fees are believed due at this time. If, however, any fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

Dated: June 19, 2009

By: /Scott S. Servilla, Reg. #40806/
Scott S. Servilla
Reg. No. 40,806
Tel.: (732) 815-0404
Attorney for Applicants

BECTON, DICKINSON AND COMPANY
1 Becton Drive
Franklin Lakes, New Jersey 07417